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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Substitute for form 1449A/PTO **INFORMATION DISCLOSURE** Complete if Known P ASSATEMENT BY APPLICANT 10/560,383 **Application Number Filing Date** March 29, 2007 **First Named Inventor** Michael G. Orchard, et al. **Art Unit** 1625 **Examiner Name** John Mabry (Use as many sheets as necessary) Attorney Docket No: AC-50-US of Sheet

US PATENT DOCUMENTS					
Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Filing Date If Appropriate
		4,407,809	10-04-1983	Junge et al.	·
		4,639,436	01-1987	Junge et al.	
		5,051,407	09-24-1991	Boshagen et al.	
		5,798,366	8-25-1998	Platt et al.	
 		6,046,214	04-04-2000	Kristiansen et al.	<u> </u>
		6,426,198	7-30-2002	Carstea et al.	
		6,495,570	12-17-2002	Jacob et al.	·····
		6,683,076	01-2004	Walkley et al.	
		7,256,005	08-2007	Zitzmann et al.	
		2001/0044453	11-22-2001	Jacob et al.	<u>.</u>
		US 2004/0019082	01-29-2004	Van der Spoel et al.	
		20060058349	3-2006	Hussein et al.	
		20060074107	04-2006	Butters et al.	
		20060111400	05-2006	Hussein et al.	
		20070112028	05-2007	Orchard et al.	
		20080234324	09-2008	Scopes et al.	

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DATE CONSIDERED

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Approved for use through 7/31/2008. OMB 0651-0031
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Sheet	2	of	4	Attorney Docket No: AC-50-US		

			FOREIGN F	PATENT DOCUMENTS	
Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	T ²
		DE 3024901 A (and Translation)	01-28-1982	Dietar et al.	
		EP 0491041	24 Jun 1992	Nippon Shinyaku Co. Ltd.	
		EP 698102	01 Mar 2006	Roche Diagnostics GmbH	
		EP 698012	29 Jan 1997	G.D. Searle & Co.	
		JP-1-02/306962	20 Dec 1990	Meiji Seika Kaisha Ltd.	
		JP 3-24057	01 Feb 1991	Tosoh Corp.	
		JP H02-306962 (and Translation)	12-20-1990	Hiroshi et al.	
		WO 92/00277	09 Jan 1992	Nippon Shinyaku Co., Ltd.	
		WO 98/02161	22 Jan 1998	Universiteit Van Amsterday	
		WO 98/30219	16 Jul 1998	Monsanto Company	
		WO 99/24401	20 May 1999	G.D. Searle & Co.	
		WO 00/33843	15 Jun 2000	G.D. Searle & Co., et al.	
		WO 00/56334	28 Sep 2000	The Trustees of Boston College	
		WO 00/62780	26 Oct 2000	Oxford Glycosciences (UK) Ltd.	
_		WO 01/10429	15 Feb 2001	Zitzmann et al.	
		WO 02/055489	07-18-2002	The Trustees of Columbia University in the City of New York	
		WO 04/007453	22 Jan 2004	Oxford Glycosciences (UK) Ltd.	
		WO 04/007454	22 Jan 2004	Oxford Glycosciences (UK) Ltd.	
		WO 04/111001	23 Dec 2004	Oxford Glycosciences (UK) Ltd.	
		WO 04/111002	23 Dec 2004	Oxford Glycosciences (UK) Ltd.	
_		WO 05/068426	28 Jul 2005	Cell-Tech R&D Limited	

	OTHER	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
-		ABE et al., Induction of glucosylceramide synthase by synthase inhibitors and ceramide, BBA, 1299, 333-341 (1996).	
		ALTER, M., GM1 ganglioside for acute ischemic stroke- trial design issues, Ann. NY Acad. Sci., 1998, 845, pp. 391-4011.	
		ASANO, K., "New entry for asymmetric deoxyazasugar synthesis: syntheses of deoxymannojirimycin, deoxyaltrojirimycin and deoxygalactostatin", Chem. Commun., 1999, pp. 41-42.	:
		ASANO, N. et al., "Novel α-L-fucosidase inhibitors from the bark of angylocalyx pynaertii (leguminosae), Eur. J. Biochem., 2001, 268, pp. 35-41.	

EXAMINER

DATE CONSIDERED

Substitute for form 1449A/PTO **INFORMATION DISCLOSURE** Complete if Known STATEMENT BY APPLICANT **Application Number** 10/560,383 **Filing Date** March 29, 2007 **First Named Inventor** Michael G. Orchard, et al. 1625 **Art Unit Examiner Name** John Mabry (Use as many sheets as necessary) Attorney Docket No: AC-50-US Sheet of

BARILI, P.L. et al., "Double reductive amination of L-arabino-hexos-5-uloses: a diastereoselective approach to 1-deoxy-D-galactostatin derivatives (#)(°)," Tetahedron, 1997, 53(9), pp. 3407-3416.	
BAXTER, E.W. et al., "Expeditious synthesis of azasugars by the double reductive amination of dicarbonyl sugars", J. Org. Chem., 1994, 59, pp. 3175-3185.	
BERG et al., Herbicidal composition containing piperidine derivatives, CAPLUS, 96:117597 (1982).	
Biochemical Genetics, A Laboratory Manual, Oxford University Press.	
BOESHAGEN et al., Use of hydroxymethyl-3,4,5-trihydroxypiperidines as antiviral agents, CAPLUS, 113:126581 (1990).	
Br. J. Cancer, 1999, 81(3), pp.423-430.	
BRAMER, SL.L. et al., Biologic activity of 5'-deoxy-5-fluorouridine by rectal administration, Pharmaceutical Res., 1989, 6(4), 318-322.	***************************************
BUTTERS et al., Therapeutic applications of imino sugars in lysosomal storage disorders, Current Topics in Medicinal Chemistry, 3, 561-574 (2003).	
CAREY, Organic Chemisry, 2 nd Edition, Pages 28-29, 268-271.	
CRUZ, J.C., et al., Fate of Endogenously Synthesized Cholesterol in Niemann-Pick Type C1 Cells, The Journal of Biological Chemistry, 2000, Issue of December 29, Vol. 275, No. 52, pp. 41309-41316.	
DRAYER et al., Clinical and Pharmacology and Therapeutics, 1986.	
EZURE et al., Preparation of 1-deoxygalactostatin derivatives as β-galactosidase inhibitors, CAPLUS, 116:236093 (1992).	
FOUACE, S. et al., Lipophilic prodrugs of 1-deoxynojirimycin derivatives, <i>Tetrahedron Letts.</i> , 2000, 41, 7313-7315.	
FOWLER, P.A. et al., Synthesis and activity towards yeast α-glucosidase of 1,5-dideoxy-1,5-imino-L-iditol (1-deoxy-L-idonojirimycin), Carbohydr. Res., 1993, 246, 377-381.	
GREENE, Protective groups in organic synthesis, Wiley-interscience Publication, pages:cover, 10, 11, 29 (1982).	
HUGEL, H.M. et al., Stereoselective electrophilic cyclizations of δ-aminoalkenes derived from carbohydrates: synthesis of polyhydroxypiperidines, Aust. J. Chem., 1998, 51, pp. 1149-1155.	
HUTT and O'GRADY, Drug Chirality, 1996.	
JARANOWSKA, A. et al., Platelet-activating factor production by human fetal microglia, Mol. & Chem. Neuropathol., 1995, 24, pp. 95-106.	_
KATO et al., Biological properties of D- and L-1 deoxyazasugars, J. Med. Chem., 48, pp. 2036-2044, (2005).	
KAZMAIER, U. et al., A short synthesis of polyhydroxylated piperidines by adol reaction of chelated amino acid ester enolates, Eur. J. Org. Chem., 1998, pp. 1833-1840.	
KURIHARA et al., Preparation of N-substituted 1-deoxynojirimycins as tumor metastasis inhibitors, CAPLUS, 114:185939 (1991).	
LE MERRER et al., Synthesis of azasugars as potent inhibitors of glycosidases, 5(3), 519-533, (1997).	
LIN and LU et al., Role of Pharmacokinetics and Metabolism in Discovery and Development, 1997.	

EXAMINER DATE CONSIDERED

PTO/SB/08a(04-07)
Approved for use through 7/31/2006. OMB 0651-0031
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LIU, Y. et al., Alleviation of neuronal ganglioside storage does not improve the clinical course of the Niemann-Pick C disease mouse, Human Molecular Genetics, 2000, Vol. 9., No. 7, pp. 1087-1092.	
MELLOR, High-performance cation-exchange chromatography and pulsed amperometric detection for the separation, detection, and quantitation of N-alkylated imino sugars in biological samples, Analytical Biochemistry, XP-001055984, 284, 136-142 (2000).	
MORRISON et al., Organic Chemistry, 5 th Edition, Pages 138-141.	
OVERKLEEFT et a., Generation of specific deoxynojirimycin-type inhibitors of the non-lysosomal glucosylceramidase, J. of Biol. Chem. 23(43), 27108-27114, (1994).	
PLATT et al., N-Butyideoxynojirimycin is a novel inhibitor of glycolipid biosynthesis, 269(11), 8362-8365 (1994).	
PLATT, F.M. et al., New Therapeutic Prospects for the Glycosphingolipid Lysosomal Storage Diseases, Biochemical Pharmacology, 1998, Vol. 56, pp. 421-430.	
POITOUT, L. et al., Synthesis of azasugars. Part 1 – Simerization of polyhydroxylated piperidines, Tetrahedron Letts., 1996, 37(10), pp. 1609-1612.	
RAO, V.S. et al., Regioselective eliminations in reactions of carbohydrate derivatives with superoxide, or with borohydride in 2-propanol, Can. J. Chem., 1981, 59(2), pp. 333-338.	
REITZ, A.B. et al., Pyrrolidine and piperidine aminosugars from dicarbonyl sugars in one step. Concise synthesis of 1-deoxyojirimycin, Tetrahedron Letts., 1990, 31(47), pp. 6777-6780.	
SCHALLER et al., Total synthesis of (+)- and (-)-1-deoxynojirimycin (1,5-dideoxy-1,5-imino-D-and L-glucitol) and of (+)- and (-)-1-deooxyidonojirimycin(1,5-didoxy-1,5-imino-D and L-iditol) via furoisoxazoline-3-aldehydes, Carbohydrate Res., 314, 25-35, (1998).	
SILVA, et al., Advances in Prodrug Design, Mini-Reviews in Medicinal Chemistry, 2005, Vol. 5, pp. 893-914.	
TESTA et al., Racemates Versus Enantiomers in Drug Development, 1990.	
VAN DEN BROEK et al., Chemical modification of aza sugars, inhibitors of N-glycoprotein-processing glycosidases and of HIV-I infection, CAPLUS, 19:96007, (1993).	
VAN DER SPOEL et al., Proc. Natl. Acac. Sci. USA, 99(26), 17173-17178 (2002).	
WU, W. et al., Synthesis and Biological Activity of a Gemcitabine Phosphoramidate Prodrug, J. Med. Chem., 2007, Vol. 50(15), pp. 3743-3746.	
YILDIZ, Y. et al., Mutation of β-gludosidase 2 causes glycolipid storage disease and impaired male fertility, The Journal of Clinical Investigation, 2006, Vol. 116, No. 11, pp. 2985-2994.	
ZERVAS, M. et al., Critical role for glycosphingolipids in Niemann-Pick disease type C, Current Biology, 2001, 11, pp. 1283-1287.	

EXAMINER DATE CONSIDERED